

# EXHIBT 2

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                |   |   |
|----------------|---|---|
| Applicant      | : | TAN, Barrie   |
| App. No.       | : | 10/823,043  |
| Filed          | : | April 12, 2004  |
| For            | : | Annatto Extract Compositions,<br>including Tocotrienols and<br>Tocopherols and Methods of Use |
| Examiner       | : | McCormick-Ewoldt, S.B.  |
| Group Art Unit | : | 1655  |

**DECLARATION UNDER 37 C.F.R. §1.131**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. I, BARRIE TAN, a citizen of the United States, hereby declare that:

2. My address is 49 Northhampton Road, Amherst, MA, 01002

3. I am the inventor of the invention in U.S. Application Serial No. 10/823,043 entitled "Annatto Extract Compositions, including Tocotrienols and Tocopherols and Methods of Use" (the "Application") filed April 12, 2004.

4. I have over 25 years experience in Chemistry, Biochemistry, and Nutrition. I received my Ph.D. in Chemistry at the University of Otago/New Zealand in 1978 and completed 2.5 years of post-Doctoral work in Biochemistry at Auburn University/Alabama (1979-1981). I have been conducting research in tocotrienols and tocopherols for more than 20 years.

5. I understand that the Examiner has rejected Claims 39, 47, and 49 under 35 USC 112, Second Paragraph has being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner has found the phrase "natural extract" to be indefinite. I use the phrase "natural extract" as defined by the FDA. The FDA defines the term "natural extract" as "a substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in

section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this definition, the term “nonsynthetic” is used by the FDA as a synonym for “natural” as the term is used in the Act.

6. I understand that the Examiner has rejected Claims 1, 37 and 38 under 35 USC 102(b) as being anticipated by Tan et al. (US 6,350,453). The Examiner has stated that Tan et al. teaches that the byproduct oil from *Bixa orellana* contains delta- and gamma-tocotrienols and it meets the limitations of Claim 1.

7. I am the inventor of Tan et al. (US 6,350,453). The byproduct oil from *Bixa orellana* disclosed in Tan et al. contains a delta- to gamma-tocotrienol ratio of 9:1. No other ratio of delta- to gamma-tocotrienol is disclosed in the ‘453 patent. Specifically, the ratios in Claims 1, 37 and 38 were not disclosed in the ‘453 patent.

8. The delta- to gamma-tocotrienol ratios in Claims 1, 37, and 38 have beneficial effects due to these ratios.

8. I understand that the Examiner has rejected Claims 47-50 under 35 USC 102(b) as being anticipated by Tan et al. (US 6,350,453) as it teaches an annatto byproduct oil and a natural extract when a vegetable oil is added to the distillation of the tocotrienols.

9. In Example 1 of the ‘453 patent, Rice bran oil was added to the Annatto oil byproduct to reduce its viscosity of the material to aid in the distillation. The Rice bran oil used in the experiment was cooking oil. Vegetable cooking oils and animal fats have molecular weights typically in the 800 - 900 Dalton range, or more broadly a range of 500 - 1000 Daltons, which includes the medium chain triglycerides in the lower range and fish oils (commonly called omega-3 fats) in the higher range.

10. A person having ordinary skill in the arts would recognize that Vitamin E, including tocopherols and tocotrienols, are typically 390 - 430 Daltons in molecular weight or more broadly 350 - 450 Daltons in molecular weight, which includes tocopherols and tocotrienols without any methylated groups in the lower range and tocopherols and tocotrienols with fully methylated groups in the higher range.

11. Also, a person having ordinary skill in the arts would be able to calculate the molecular weights of the isomers of tocopherol and tocotrienol from their chemical structures as: Alpha-Tocopherol = 430, Beta-Tocopherol = 417, Gamma-Tocopherol = 417, Delta-Tocopherol = 403, Alpha-Tocotrienol = 424, Beta-Tocotrienol = 411, Gamma-Tocotrienol = 410, and Delta-Tocotrienol = 396.

12. It would be clear to a person having ordinary skill in the arts that the molecular weight of triglycerides is about 2 times higher than that of vitamin E.

13. The use of the phrase "appropriate spectrum of tocols" refers to a mixture of the 350 - 450 Dalton molecular weight fractions of natural extracts and not to a mixture of the triglycerides in the 500 to 1,000 Dalton molecular weight fractions of the natural extracts.

14. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. Moreover, these statements were made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

December 31, 2006  
Date

/Barrie Tan/  
Barrie Tan